

FORM PTO-1399 (Modified)
(REV 10-95)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

K0208.014

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5)

09/720762

INTERNATIONAL APPLICATION NO.

PCT/JP99/03459

INTERNATIONAL FILING DATE

29 June 1999

PRIORITY DATE CLAIMED

29 June 1998

TITLE OF INVENTION

GASKET FOR PRE-FILLED SYRINGE AND PRE-FILLED SYRINGE

APPLICANT(S) FOR DO/EO/US

YANASE, Kazuyuki, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☒ Certificate of Mailing by Express Mail
19. ☒ Other items or information:

International Preliminary Examination Report**PTO-1449****PCT/RO/101****PCT/IB/301****PCT/IB/304****PCT/IB/308****PCT/IB/332****PCT/306 (mailed on Jan. 12, Jan. 19 and Sep. 28, 2000)****Notification of Change of Applicant filed on August 11, 2000**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5) 09/720762		INTERNATIONAL APPLICATION NO. PCT/JP99/03459		ATTORNEY'S DOCKET NUMBER K0208,014	
20. The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) : <input type="checkbox"/> Search Report has been prepared by the EPO or JPO \$930.00 <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) \$720.00 <input type="checkbox"/> No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$790.00 <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$1,070.00 <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$598.00				CALCULATIONS PTO USE ONLY <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$910.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). <input type="checkbox"/> 20 <input type="checkbox"/> 30				\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	5 - 20 =	0	x	\$0.00	
Independent claims	1 - 3 =	0	x	\$0.00	
Multiple Dependent Claims (check if applicable) <input checked="" type="checkbox"/>				\$270.00	
TOTAL OF ABOVE CALCULATIONS =				\$1,180.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input type="checkbox"/>				\$0.00	
SUBTOTAL =				\$1,180.00	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30 +				\$0.00	
TOTAL NATIONAL FEE =				\$1,180.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input checked="" type="checkbox"/>				\$40.00	
TOTAL FEES ENCLOSED =				\$1,220.00	
				Amount to be: refunded	\$
				charged	\$

- ☒ A check in the amount of **\$1,220.00** to cover the above fees is enclosed.
- ☐ Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **16-0633** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer No. 23723

Benjamin Levi
SIGNATURE

Benjamin Levi

NAME

37,517

REGISTRATION NUMBER

December 28, 2000

DATE

ATTORNEY DKT NO.: K0208.014

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: YANASE, Kazuyuki, et al. Group Art Unit: Not Yet Known
International Filing Date: 29 June 1999
Priority Date: 29 June 1998
International Application No.: PCT/JP99/03459
U.S. Serial No.: Not Yet Assigned Examiner: Not Yet Known
U.S. Filing Date: Herewith
For: GASKET FOR PRE-FILLED SYRINGE AND PRE-FILLED SYRINGE

Honorable Commissioner of Patents & Trademarks
Washington, D.C. 20231
BOX PCT APPLICATION

December 28, 2000

PRELIMINARY AMENDMENT

Sir:

Please amend the above-identified application as follows:

IN THE CLAIMS

1. A gasket [used] for a pre-filled syringe into which liquid is charged, wherein a peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel is provided with a restriction, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered shape.

2. The [A] gasket according to claim 1, wherein hardness of the gasket is 55 to 60 when the hardness is measured by a JIS hardness meter.

3. The [A] gasket according to claim 1, wherein one or both of the peripheral side surface that is in contact with an inner surface of the syringe barrel and [/or] a bottom surface that is in contact with liquid is laminated with polyethylene fluoride resin.

4. The [A] pre-filled syringe into which liquid is charged and tightly closed with the gasket described in [any one of] claims 1, 2 or [to] 3.

5. The [A] pre-filled syringe according to claim 4, wherein the liquid is contrast medium.


REMARKS

The above-identified application has been amended with this national stage filing to conform the claims to U.S. practice. No new matter is presented.

In view of the present amendments, Applicants believe the present application is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

Dated: December 28, 2008



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SPECIFICATION**Gasket for Pre-Filled Syringe and Pre-Filled Syringe**Field of the Invention

The present invention relates to a gasket for a pre-filled syringe and the pre-filled syringe.

Background Art

In generally, chemical liquid is charged into a syringe barrel when it is used. In recent years, a pre-filled syringe in which chemical liquid is previously charged into the syringe barrel has been developed, and working load in medical site is reduced. Recently, a pre-filled syringe in which contrast medium is charged into the syringe is also used. Since the contrast medium has relatively high viscosity, it is considered that it is important to increase sliding ability of a gasket so as to reduce the charging pressure. Especially when a syringe barrel is made of polymeric resin, since the sliding ability of the gasket is inferior, silicon oil is applied onto a peripheral side surface of a gasket that is in contact with an inner surface of the syringe barrel to enhance the sliding ability, or polyethylene fluoride resin such as Teflon (registered trade name) is laminated. However, if silicon applied to a gasket is mixed into chemical liquid, it becomes foreign matter, this may cause product defect, and there is apprehension that such foreign matter may have toxicity to human body.

It is normal that the pre-filled syringe is sterilized after chemical liquid is charged or chemical liquid is charged in axenic conditions. Sterilization after charging is carried by heating the pre-filled syringe for

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example, but it is important to form the gasket into such a shape that high pressure chemical liquid caused by heat at the time of sterilization is not leaked. When polyethylene fluoride resin or the like is laminated on a gasket, since the polyethylene fluoride resin is hard, if the gasket is inserted into the syringe barrel, fine wrinkles may be generated on a peripheral side surface of the gasket, and chemical liquid may be leaked through the wrinkles at the time of sterilization.

The present inventor studies hard to solve these problems and as a result, the inventor invented the following inventions.

Summary of the Invention

According to claim 1, there is provided a gasket used for a pre-filled syringe into which liquid is charged, wherein a peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel is provided with a restriction, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered shape.

In this gasket of claim 1, as described in claim 2, it is preferable that hardness of the gasket is 55 to 60 when the hardness is measured by a JIS hardness meter. Further, as described in claim 3, it is preferable that the peripheral side surface that is in contact with the inner surface of the syringe barrel and/or a bottom surface that is in contact with liquid is laminated with polyethylene fluoride resin.

According to claim 4, there is provided a pre-filled syringe into which liquid is charged and tightly closed with the gasket described in any one of claims 1 to 3.

In this pre-filled syringe of claim 4, the liquid is, for example,

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contrast medium as described in claim 5.

In the gasket of claims 1 to 3 and the pre-filled syringe of claims 4 and 5, the gasket plays a role as a lid for tightly closing the liquid charged into the syringe barrel, and also plays a role as a piston when the pre-filled syringe is used. As the JIS hardness meter for measuring the hardness of the gasket, "Durometer" produced by Shimazu Seisakusho can be used for example. A preferable range of the hardness of the gasket measured by the JIS hardness meter is 57 to 59. Material of the gasket is not limited only if it has appropriate hardness, but usually, the material is normal butyl rubber, silicon rubber or polymeric resin, and more preferably, chlorinated butyle rubber.

The peripheral side surface that is in contact with the syringe barrel or the bottom surface that is in contact with liquid can be laminated with polyethylene fluoride resin using a conventionally known laminating method. Silicon may be applied to the peripheral side surface of the gasket that is in contact with the inner surface of the syringe barrel, but it is preferable that silicon is not applied to the bottom syringe that is in contact with the liquid charged into the syringe barrel. The silicon can also be applied by a conventionally known application method.

Material of the syringe barrel is not limited, and any of glass and resin can be used. Especially, resin is preferable, and example of the material is annular polyolefin fiber.

Liquid to be charged into the syringe barrel is not limited to the contrast medium, and liquid other than the contrast medium may be used. Example of contrast medium is iomeprole. An amount of liquid to be charged into the syringe barrel is usually about 10 to 200 ml, and

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more preferably 50 to 100 ml.

Brief Description of the Drawings

Fig.1 is a sectional view of a pre-filled syringe according to an embodiment of the present invention; and

Fig.2 is a side view of a gasket according to the embodiment of the invention.

Detailed Description of the Preferred Embodiments

A preferred embodiment of the present invention will be explained with reference to the accompanying drawings below.

As shown in Fig.1, in a pre-filled syringe 1 of this embodiment, a contrast medium 3 as one example of chemical liquid is charged in a cylindrical syringe barrel 2. The syringe barrel 2 is made of annular polyolefin fiber for example. The syringe barrel 2 is provided at its tip end (left end of the syringe barrel 2 in Fig.1) with a nozzle 4. The nozzle 4 is formed with a lure lock 5, and by mounting a cap 6 on the lure lock 5, the nozzle 4 is tightly closed. A columnar gasket 7 is inserted into the syringe barrel 2 from an opened rear end (right end of the syringe barrel 2 in Fig.1) of the syringe barrel 2, and the contrast medium 3 in the syringe barrel 2 is tightly closed by the gasket 7.

The gasket 7 is made of chlorinated butyle rubber for example, and the gasket 7 preferably has hardness of 55 to 60 degrees, more preferably 57 to 59 degrees when the hardness is measured using JIS hardness meter. As shown in Fig.2, a peripheral side surface 7a of the gasket 7 that is in contact with an inner surface of the syringe barrel 2 is formed with an annular restriction 8. A depth a of the restriction 8 is

about 0.05 to 1.0 mm, and more preferably, 0.1 to 0.5 mm if the gasket has a diameter b of 30 to 35 mm and a height c of 15 to 18 mm.

A bottom surface 7b (lower surface of the gasket 7 in Fig.2) that is in contact with the contrast medium 3 charged into the syringe barrel 2 is formed into a conical surface. The bottom surface 7b and the peripheral side surface 7a are laminated with polyethylene fluoride resin.

A central portion of a bottom surface 7c (upper surface of the gasket 7 in Fig.2) that is not in contact with the contrast medium 3 charged into the syringe barrel 2 is formed, as shown in Fig.2, with a threaded hole 9 into which a rod is fitted. As shown in Fig.2, a periphery of the bottom surface 7c is formed into a tapered slant 10. A range (range of the gasket 7 from an outer diameter in its diametrical direction) d where the slant 10 is formed is about 0.5 to 5 mm, and more preferably about 1 to 3 mm if the gasket has a diameter b of 30 to 35 mm and a height c of 15 to 18 mm.

According to this pre-filled syringe 1 having the above-described structure, the cap 6 is removed from the nozzle 4, and a tip end of an extension tube (not shown) for example is threadedly fitted to the lure lock 5. A rod (not shown) is fitted to the bottom surface 7c of the gasket 7. Then, the rod is pushed to push out the contrast medium 3 in the syringe barrel 2 through the extension tube, thereby charging the contrast medium 3 into a target position.

Industrial Applicability

According to the inventions of claims 1 to 5, the sliding ability when polyolefin resin is used as material of a syringe barrel is used is

remarkably enhanced, and liquid is not leaked almost at all when the pre-filled syringe is sterilized. The gasket can smoothly move at the time of sterilization even when the gasket is pushed out, and there is no adverse possibility that the gasket is diagonally inclined with respect to a center axis of the syringe barrel.

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WHAT IS CLAIMED IS:

1. A gasket used for a pre-filled syringe into which liquid is charged, wherein a peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel is provided with a restriction, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered shape.
2. A gasket according to claim 1, wherein hardness of the gasket is 55 to 60 when the hardness is measured by a JIS hardness meter.
3. A gasket according to claim 1, wherein the peripheral side surface that is in contact with an inner surface of the syringe barrel and/or a bottom surface that is in contact with liquid is laminated with polyethylene fluoride resin.
4. A pre-filled syringe into which liquid is charged and tightly closed with the gasket described in any one of claims 1 to 3.
5. A pre-filled syringe according to claim 4, wherein the liquid is contrast medium.

DESCRIPTION OF CHARACTERS

- 1 pre-filled syringe
- 2 syringe barrel
- 3 contrast medium
- 4 nozzle
- 5 lure lock
- 6 cap
- 7 gasket
- 7a peripheral side surface
- 7b ,7c bottom surface
- 8 annular restriction
- 9 threaded hole
- 10 tapered slant

ABSTRACT OF THE DISCLOSURE

A gasket 7 used for a pre-filled syringe 1 into which liquid 3 is charged, wherein a peripheral side surface of the gasket 7 that is in contact with an inner surface of the syringe barrel 2 is provided with a restriction 8, and a periphery of a bottom surface 7c of the gasket 7 that is not in contact with the liquid 3 is formed into a tapered shape.

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FIG.1

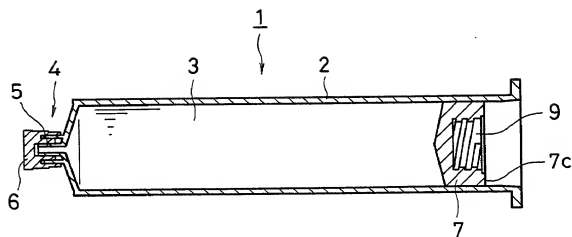
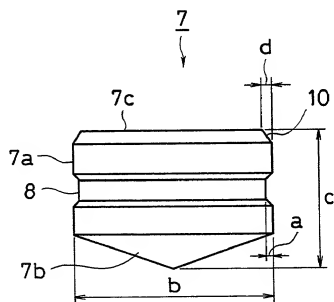


FIG.2



COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Includes Reference to PCT International Applications)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Gasket for Pre-Filled Syringe and Pre-Filled Syringe

the specification of which (check only one item below):

- ☐ is attached hereto.
- ☐ 1 was filed as United States application
Serial No. on
and was amended on (if applicable).
- ☒ 2 was filed as PCT international application
Number PCT/JP99/03459 on June 29, 1999
and was amended under PCT Article 19
on (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56 (a).

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Includes Reference to PCT International Applications)

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119	
Japan	JP-10-183005	June 29, 1998	<input checked="" type="checkbox"/> 5 YES	<input type="checkbox"/> 6 NO
PCT	PCT/JP99/03459	June 29, 1999	<input checked="" type="checkbox"/> 7 YES	<input type="checkbox"/> 8 NO
			<input type="checkbox"/> 9 YES	<input type="checkbox"/> 10 NO
			<input type="checkbox"/> 11 YES	<input type="checkbox"/> 12 NO
			<input type="checkbox"/> 13 YES	<input type="checkbox"/> 14 NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS			STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE		PATENTED	PENDING	ABANDONED
PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Includes Reference to PCT International Applications)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) with full power of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

John M. DiMatteo (Reg. No. 32,690) (1)

Send Correspondence to:			Direct Telephone Calls to: (name and telephone number)	
<u>John M. DiMatteo</u> <u>PATTERSON, BELKNAP, WEBB & TYLER, LLP</u> <u>1133 Avenue of the Americas</u> <u>New York, New York 10036-6710</u>			<u>John M. DiMatteo</u> <u>(212) 336-2000</u>	
201	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY	
202	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY	
203	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY	

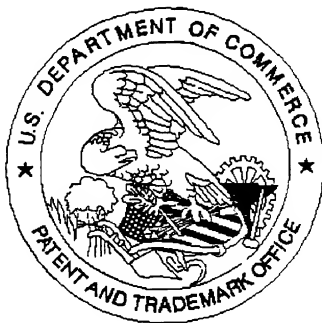
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201 <u>Kazuyuki Yanase</u>	SIGNATURE OF INVENTOR 202 <u>Keizou Nakamoto</u>	SIGNATURE OF INVENTOR 203 <u>Kazumi Fujima</u>
DATE <u>Dec 21, 2000</u>	DATE <u>Dec 21, 2000</u>	DATE <u>Dec 21, 2000</u>



Additional inventors are being named on the attached sheet(s).

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